k122083

510(k) Summary

ELITech Clinical Systems CK NAC SL

AUG 22 2012

1. Date: July 11, 2012
2. Submitter: ELITech Clinical Systems SEPPIM S.A.S
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61500 SEES
FRANCE

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4. Device Description: ELITech Clinical Systems CK NAC SL
Classification: Class II
JHW
Clinical Chemistry
21 CFR 862.1215

Device Description: ELITech Clinical Systems ELICAL 2
Classification: Class II
JIX
Clinical Chemistry
21 CFR 862.1150

Device Description: ELITech Clinical Systems ELITROL I and ELITROL II
Classification: Class I, reserved
JJY
Clinical Chemistry
21 CFR 862.1660

5. Predicate Device: k063744
Roche Diagnostics
CKL

k033501
Roche Diagnostics
Calibrator for Automated Systems (C.f.a.s.)

k041227
Roche Diagnostics
Precinorm and Precipath

6. Intended Use

Reagents: ELITech Clinical Systems CK NAC SL is intended for the quantitative *in vitro* determination of creatine kinase (CK) in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings. Creatine phosphokinase and its isoenzymes measurements are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as

progressive, Duchenne-type muscular dystrophy.

Calibrators: ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Controls: ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Special conditions for use statement(s):
Prescription Use Only. It is not intended for use in Point of Care settings.

Special instrument requirements:
Performance was provided for the ELITech Clinical Systems Selectra ProM.

7. **Device Description**
CK NAC SL is available as kit only. It consists of 2 reagents R1 & reagent R2:
Reagent R1 contains: Imidazole buffer (pH 6.10), D-Glucose, N-Acetyl-L-Cysteine, Magnesium acetate, NADP, EDTA, Hexokinase (microorganisms), sodium azide.
Reagent R2 contains: Creatine phosphate, ADP, AMP, Diadenosine pentaphosphate, Glucose-6-phosphate Dehydrogenase (G-6-PDH) (micro-organisms), sodium azide.

ELITech Clinical Systems ELICAL2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration. ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to the antibodies to HCV and HIV according to FDA-approved methods.

ELITROL I and ELITROL II are two level quality control products consisting of a lyophilized human serum containing constituents at desired levels. ELITROL I and ELITROL II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods.

8. **Substantial Equivalence Information -**
Assay
1. Predicate Device Name
   Roche Diagnostics CKL
2. k063744
3. Comparison with predicate

Similarities

Parameter	CK NAC SL	Roche Diagnostics CKL
Intended Use	Intended for the quantitative *in vitro* determination of creatine kinase (CK) in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	*In vitro* test for the quantitative determination of creatine kinase (CK) in human serum and plasma on the cobas c111 system.

Specimen Type	Serum and Plasma free of hemolysis[1,2]	Same
Assay Technology	Kinetic U.V. method	Same
Calibration frequency	28 days	Same

Differences

Parameter	CK NAC SL	Roche Diagnostics CKL
Assay Range	10 – 1714 U/L	7 – 2000 U/L
Instrument	Selectra ProM analyzer	cobas c111
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Roche Calibrator f.a.s.
Interference	**Triglycerides:** No significant interference up to 3000 mg/dL. **Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 mol/L). **Ascorbic acid:** No significant interference up to 20.0 mg/dL. **Acetaminophen:** No significant interference up to 30.0 mg/dL. **Acetylsalicylic acid:** No significant interference up to 200.0 mg/dL.	**Hemoglobin:** No significant interference up to an H Index of 100 (approximate 100 mg/dL). **Lipemia (Intralipid):** No significant influence up to an L index of 1000. **Icterus:** No significant influence up to I Index of 15 (approximate conjugated and unconjugated bilirubin concentration of 15 mg/dL (257µmol/L)).
Reference Range	Serum/plasma: [3] Men: < 171 U/L Women: < 145 U/L	Serum/plasma: Men: < 191 U/L Women: < 170 U/L

Control

1. Predicate Device Name:
   Roche Diagnostics Precinorm U and Precipath U
2. k041227
3. Comparison with predicate

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[1] Hørder M, Elser RC, Gerhardt W, Mathieu M. Sampson EJ.International Federation of Clinical Chemistry, Committee on Enzymes. Approved recommendation on IFCC methods for the measurement of catalytic concentration for enzymes. Part 7. IFCC method for creatine kinase. Eur.J Clin Chem Clin Biochem 1991; 29:435-56.

[2] Gerhard Schumann, Roberto Bonora, Ferruccio Ceriotti, Pascale Clerc-Renaud, Carlo A. Ferrero, IFCC Primary Reference Procedures for the Measurement

of Catalytic Activity Concentrations of Enzymes at 37°C Part 2. Reference Procedure for the Measurement of Catalytic Concentration of Creatine Kinase, Clin Chem Lab Med 2002; 40(6):635–642.

[3] Schumann, G., *et al.*, Clin. Chem. Lab. Med., (2002), **40**, 635-42.

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems ELITROL I and ELITROLII)	Predicate Roche Diagnostics Precinorm U and Precipath U (k041227)
Intended Use/Indications for Use	ELITech Clinical Systems ELITROL **I** and ELITROL **11** are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	Precinorm U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets. Precipath U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Format	Lyophilized human sera with constituents added as required to obtain defined component levels	Same
Levels	Two Levels (Level I and Level II)	Same
Stability	Lyophilized: Store at 2-8°C and protected from light until the expiry date. After Reconstitution: 12 hours between 15-25°C, 5 days between 2-8°C, 4 weeks between -25 and -15°C (when frozen once)	Same

Calibrator

1. Predicate Device Name:
   Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)
2. k033501
3. Comparison with predicate

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems ELICAL 2)	Predicate Roche Calibrator for Automated Systems (C.f.a.s.) k033501
Intended Use/Indications for Use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.	Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.
Format	Lyophilized calibrator based on human serum with constituents added as	Same

	requires to obtain desired component levels	
Level	Single Level	Same
Stability	Lyophilized: store at 2-8°C and protect from light until the expiry date. After reconstitution: 8 hours - between 15-25°C, 2 days between 2-8°C, 4 weeks between -25 and -15°C (when frozen once)	Same

9. **Standard/Guidance Document Reference**

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP5-A2, Vol 24, No. 25, August 2004.
- Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline. CLSI (NCCLS) document EP17-A, vol 24, No. 34, October 2004.
- Method Comparison and Bias estimation Using Patient Samples; Approved Guideline—Second Edition. CLSI (NCCLS) document EP9-A2-IR, Vol 30, No. 17, July 2010.
- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use: Guidance for Industry and FDA Staff, November 2004.
- Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition. CLSI (NCCLS) document EP07-A2, Vol 25, No. 27, November 2005.
- Evaluation of the Linearity of the Measurement of Quantitative Procedures: a Statistical Approach; Approved Guideline. CLSI (NCCLS) document EP6-A, Vol 23, No. 16, April 2003.

10. **Test Principle:**

UV Method.

$$\text{Creatine Phosphate} + \text{ADP} \xrightarrow{\text{Creatine kinase}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{D-Glucose} \xrightarrow{\text{Hexokinase}} \text{D-Glucose-6-Phosphate} + \text{ADP}$$

$$\text{G-6-P} + \text{NADP}^{+} \xrightarrow{\text{G-6-PDH}} \text{D-Gluconate-6-Phosphate} + \text{NADPH} + \text{H}^{+}$$

Where:
G-6-P: D-Glucose-6-Phosphate and G-6-PDH: Glucose-6-Phosphate Dehydrogenase.

The increase of NADPH concentration is directly proportional to the enzymatic CK activity.

11. **Performance Characteristics – Analytical Performance**

a. Precision/Reproducibility

The precision of the device was determined in accordance with Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP5-A2, Vol 24, No. 25, August 2004.

Within-run and Total precision results were obtained by performing two runs per day, two measures per run, for 3 levels of samples on 2 instruments during twenty operating days according to CLSI EP5-A2 protocol. The results are presented in the table below:

Within-Run Precision

	n	Mean (U/L)	Within-run SD	Within-run CV%
Level 1	80	147	1.0	0.7
Level 2	80	406	4.6	1.1
Level 3	80	1154	13.1	1.1

Total Precision

	n	Mean (U/L)	Total SD	Total CV%
Level 1	80	147	2.4	1.7
Level 2	80	406	9.8	2.4
Level 3	80	1154	45.5	3.9

b. Linearity/assay reportable range

The linearity study of CK NAC SL reagent was performed according to CLSI protocol EP6-A. From this study, a measuring range from 10 to 1714 U/L has been determined.
Manual dilution 1 to 10 allows an upper linearity of CK NAC SL reagent to 17140 U/L.

c. Traceability

For calibration, a multi-parametric calibrator named ELITech Clinical Systems ELICAL 2 (manufactured by SEPPIM under product code CALI-0580) must be used. Its value is traceable to the IFCC method (Schumann, 2002), by manual measurement.
The values of these control materials are traceable to the IFCC method (Schumann, 2002), by manual measurement.

d. Stability

Real-time stabilities:
On board stability for the ELITech Clinical Systems CK NAC SL was established by real time studies on the ELITech Clinical Systems Selectra ProM. The on-board stability of the reagent is 28 days. The shelf-life of CK NAC SL reagent has been followed in the real time

for 14 months on 3 different batches.

Control material is purchased from a commercial vendor (previously cleared under k041227). The following is claimed for stability: Before reconstitution, the shelf-life of the ELITech Clinical Systems Elitrol 1 and Elitrol II is 30 months at 2-8°C. After reconstitution the stability is 12 hours when stored at 15-25°C, 5 days when stored at 2-8°C or 4 weeks (when frozen once) at -25° and -15° C.

Calibrator material is purchased from a commercial vendor (previously cleared under k033501). The following is claimed for stability: Elical 2 is stable until the expiration date printed on the label when stored at 2-8°C prior to reconstitution. After reconstitution the stability is 8 hours when stored at 15-25°C, 2 days at 2-8°C or 4 weeks (when frozen once) at -25°and -15°C. The labeling stated that the Elical 2 should be stored tightly capped and protected from light when not in use.

Value Assignment
Elitrol I and II are value assigned using multiple Vital Scientific PRO M analyzers. Each sample is tested in triplicate over several days. The target value of Level I and II are the median of the observed values range. After validation of the target value, a confidence range (high and low values) is then calculated.

Elical 2 is tested against predetermined values on multiple Vital Scientific PRO M using the CL NAC SL reagent and 2 levels of quality control material. The mean analyte value is calculated and a target value is assigned.

e. Detection limit

Determined according to CLSI protocol EP17-A (Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline).

Limit of Detection (LoD) of CK NAC SL obtained from 15 measurements of 4 samples with a low concentration of analyte (approximately 4 x LoB ~ 2.4 U/L) is 1 *U/L*.

Limit of Quantification (LoQ) of CK NAC SL obtained from 15 measurements of 4 samples at nominal concentration 5 U/L is *5 U/L*.

f. Interference/analytical specificity

Interferences due to unconjugated bilirubin, conjugated bilirubin, triglycerides, acetaminophen, ascorbic acid, acetylsalicylic acid were investigated following the recommended sample levels in CLSI EP7-A2 protocol (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition).
The results of testing interferences are the following:

- Concentration up to 30.0 mg/dL unconjugated bilirubin, 29.5 mg/dL unconjugated bilirubin, and 3133 mg/dL triglycerides do not show any significant interference for each substance. Non-significant interference is defined as within ± 10% recovery.
- Likewise, concentrations up to 30 mg/dL acetaminophen, 20.0 mg/dL ascorbic acid and 200 mg/dL acetylsalicylic acid do not show any significant interference for each substance. Non-significant interference is defined as within ± 10% recovery.

The following statement will also be included in the labeling:

Other compounds may interfere. Users should refer to the two following literature

references:
-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).
-Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.

12. **Performance Characteristics – Comparison Studies**

a. Method comparison

A correlation study was performed between CK NAC SL reagent on a Selectra ProM analyzer and Roche Diagnostics CKL (Creatine kinase) reagent on a cobas c111 analyzer according to CLSI EP9-A2 protocol (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).
This study was performed using 100 serum patient samples from 10 to 1712 U/L over a span of 5 days.
Regression analysis of the results yielded the following:

$y = 1.012\ x + 2$ U/L
$r = 0.998$
$r^2 = 0.995$
Standard error of the estimate $Sy.x = 29$ U/L.

b. Comparison study: Matrix comparison

40 paired serum and plasma (in lithium heparin samples, ranging from 11 to 1672 U/L, were tested on Selectra ProM analyzer according to CLSI protocol EP9-A2 (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).
Regression analysis of the results yielded the following:
$y = 0.939\ x + 9$ U/L
$r = 1.000$
$r^2 = 1.000$
Standard error of the estimate $Sy.x = 9$ U/L.

c. Expected values/Reference Range

As indicated in the instructions for use for CK NAC SL, each laboratory should establish and maintain its own reference values. The values given are used as guidelines only.

Men:	Women:
< 171 U/L	< 145 U/L

These values are from "Schumann, G., *et al.*, Clin. Chem. Lab. Med., (2002), **40**, 635-42."

d. Clinical Studies:

Not applicable

e. Clinical Cut-off:

Not applicable

13. **Conclusion**

The information on the principle and performance of our device that is contained in this premarket notification is complete and supports a decision that our device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

ELITechgroup
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Suite 150
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AUG 2 2 2012

Re: k122083
Trade Name: ELITech Clinical Systems CK NAC SL
ELITech Clinical Systems ELICAL2
ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II
Regulation Number: 21 CFR §862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Codes: JHW, JIX, JJY
Dated: July 13, 2012
Received: July 16, 2012

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K122083

Device Name: ELITech Clinical Systems CK NAC SL

Indications for Use:

ELITech Clinical Systems CK NAC SL is intended for the quantitative *in vitro* determination of creatine kinase (CK) in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

It is not intended for use in Point of Care settings.

Creatine phosphokinase and its isoenzymes measurements are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Iyung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122083

Indications for Use Form

510(k) Number (if known): K122083

Device Name: ELITech Clinical Systems ELICAL 2

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems on ELITech Clinical Systems Selectra analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122083

Indications for Use Form

510(k) Number (if known): K122083

Device Name: ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) K122083